

Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

June 22, 2015

Summit Medical Inc. Ms. Nicole Dove Quality Assurance/Regulatory Affairs Manager 815 Northwest Pkwy, Suite 100 St. Paul, MN 55121

Re: K150540

Trade/Device Name: Instru-Safe® Instrument Protection System

Regulation Number: 21 CFR 880.6850 Regulation Name: Sterilization Wrap

Regulatory Class: II Product Code: KCT Dated: May 20, 2015 Received: May 22, 2015

Dear Ms. Dove:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number (A	if known)					
K150540						
Device Name Instru-Safe® Ins	trument Prot	ection Syste	em			
sterilized by a l of the enclosed Protection Syst	nstrument P healthcare p medical de em cassette Instru-Safe	rotection S provider. In vices durings are intended Instrumen	nstru-Safe Instrum ag Amsco V-PRO ded to be used in our t Protection System	nent Protection System Low Temperature Ste conjunction with a leg	d protect other medical of cassettes are intended erilization Cycles. The fally marketed wrap or Astended on their own to a	to allow sterilization Instru-Safe Instrumen Aesculap rigid
Amsco V-PRO	Low Temp	erature Ste	erilization Cycles:			
Sterilizer	Standard	Lumen	Non Lumen			
	Cycle	Cycle	Cycle			
V-PRO 1	X	N/A	N/A			
V-PRO 1 Plus	N/A	X	X			
V-PRO maX	N/A	X	X			
•	Summit Me	*J *J dical for us erile barries		RO Low Temperature	Sterilization systems Ol should not exceed the lo	_
	8	JI				
Lumen size of	instrumenta	tion valida	ted includes:			
Summit Casset	te Model	Minimum	Inside Diameter	Maximum Length	Number of Lumens	
IN-8823		3 mm		400 mm	2	
IN-6105		3 mm		200 mm	1	
IN-2681		1 mm		64 mm	1	
The worst case	validated lo	oad by ven	t-to-volume calcu	lation is the IN-2681 t	ray.	
Type of Use (Set	lect one or bo	oth, as appli	cable)			

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Over-The-Counter Use (21 CFR 801 Subpart C)

Prescription Use (Part 21 CFR 801 Subpart D)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



Indications for Use Statement

Table 1 – Device Models

Part Number	Maximum # of Instruments	Estimated Weight - Tray w/ instruments (lbs)
IN-1315	30	3.5
IN-2006	8	2
IN-2681	13	0.64
IN-2682	13	0.89
IN-2683	13	1.39
IN-2840	36	8.75
IN-2842	24	6.5
IN-2843	36	8.75
IN-2880	56	12.1
IN-2900	22	4.18
IN-2950	12	4.1
IN-3030	34	9.5
IN-4000	20	3.2
IN-4003	30	3.25
IN-4010	10	1.98
IN-5009	8	5
IN-5401	6	2
IN-5401-02	2	1
IN-5401-03	2	1
IN-5401-08	8	3.2
IN-5401-12	12	3.25
IN-6103	2	2.15
IN-6105	2	2.15
IN-6110	3	2.15
IN-6203	2	2.75
IN-6205	2	2.75
IN-6210	2	2.75
IN-6240	2	2.75
IN-6303	2	3.28
IN-6305	2	3.28
IN-6310	2	3.28
IN-6403	2	3.28
IN-6405	2	3.28
IN-6410	2	3.28



IN-6500	30	12.5
IN-7010	2	2
IN-7012	1	1.07
IN-7020	30	8.5
IN-7030	30	10
IN-7032	2	1.1
IN-7073	10	5
IN-7120	45	11.25
IN-7123	45	12
IN-7130	45	13.5
IN-7140	45	14.5
IN-7150	8	1.9
IN-7153	6	1.7
IN-7220	45	14.5
IN-7223	10	9.2
IN-7230	45	14.5
IN-7234	45	14.5
IN-7240	45	14.5
IN-7250	45	14.5
IN-7252	25	8
IN-7260	45	14.5
IN-7273	10	6
IN-7274	30	8
IN-7322	45	14.5
IN-7323	45	14.5
IN-7343	45	14.5
IN-7344	1	4
IN-7360	45	14.5
IN-7423	45	14.5
IN-7452	10	8
IN-7453	10	8
IN-7540	45	14.5
IN-7560	45	14.5
IN-7644	45	14.5
IN-7723	15	7.18
IN-7724	15	7.2
IN-7725	10	9.5
IN-7781	45	14.5



	III 6 6 7 6 4	
IN-7823	45	14.5
IN-7830	45	14.5
IN-7840	45	13.5
IN-7940	20	13.25
IN-8240	20	13.5
IN-8610	2	6.65
IN-8612	2	6.8
IN-8613	2	6.1
IN-8615	2	5.8
IN-8616	2	5.8
IN-8620	3	7.2
IN-8621	4	7.18
IN-8622	4	7.18
IN-8630	3	6.5
IN-8632	3	6.45
IN-8633	3	6.8
IN-8640	4	5.35
IN-8642	4	5.35
IN-8643	5	5.35
IN-8645	4	5.35
IN-8650	4	5.85
IN-8660	4	5.35
IN-8662	4	5.35
IN-8663	3	5.5
IN-8700	40	14
IN-8810	20	13.5
IN-8820	15	8.75
IN-8823	45	14
IN-8830	15	8.75
IN-8833	45	14
IN-8840	20	13.75
IN-8850	15	8.75
IN-8853	45	14
IN-8860	15	8.75
IN-8862	30	10.5
IN-8863	45	14
IN-8880	2	3.28
IN-8882	16	12.1



	111 0 0 1 0 0	
IN-8883	2	3.28
IN-8884	4	5.35
IN-8885	1	2.25
IN-8886	6	12.1
IN-8889	6	12.1
IN-8891-S	1	2
IN-8891-SI-12-S	1	2
IN-8891-SI-85-S	1	2
IN-8892	12	12.1
IN-8893	9	7.5
IN-8894	5	16.1
IN-8897	8	6
IN-8898	10	10.25
IN-8899	7	6.5
IN-8901	1	2.25
IN-8902-G2	22	17
IN-8903	15	13.25
IN-8904	22	17
IN-8907	7	12.5
IN-8931	1	2.4
IN-8932	9	9.5
IN-8933	3	3.75
IN-8936	6	11.5
IN-8937	16	14.5
IN-8938	8	12.5
IN-8939	10	11.6
IN-8940	5	5.18
IN-8942	11	10
IN-8943	1	2.7
IN-8944	6	4.7
IN-8945	2	5.18
IN-8946	9	6.1
IN-8980	20	9.5
IN-8982-01	17	9.5
IN-8983-01	16	9.5
IN-8984-01	15	9.5
IN-8986-S	2	6.5
IN-8987-S	2	6.5



IN-8988-S	2	6
IN-8989-S	2	6
IN-9999-160	6	12.1
IN-9999-162-S	2	5.8
IN-9999-168-S	2	5.8
IN-9999-172-S	2	5.8
IN-9999-178-S	2	5.8



510(k) Summary

Following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92

Submitter:	Summit Medical Inc. 815 Northwest Parkway, Suite 100 St. Paul, MN 55121 Tel: (651) 789-3939
ER Number:	3008719017
Contact	Nicole Dove
Person:	QA/RA Manager Tel: (651)
	789-3921
	ndove@summitmedicalusa.com
Date Prepared:	June 22, 2015
Subject	Trade Name(s):
Device:	Instru-Safe® Instrument Protection System
	Classification Name:
	Sterilization wrap containers, trays, cassettes & other accessory (21 CFR 880.6850
	Stermization wrap containers, trays, cassettes & other accessory (21 Cr R 000.0050
	Common Name:
	Instrument Tray, Sterilization Tray, Sterilization Cassettes, Instrument Delivery
	System
	Device Class:
	Class II
	Davies Code
	Device Code: KCT
	KC1
	Panel:
	General Hospital
Predicate	Tradename: Instru-Safe Instrument Protection System
Device:	510(k) Holder: Summit Medical Inc.
	510(k) #: K133015
Device	Summit Medical Inc. Instru-Safe Instrument Protection System are cassettes /
Description:	trays used to enclose and hold surgical instruments and accessories in an
	organized manner during the sterilization process and subsequent storage and
	transportation. The cassettes / trays by themselves do not maintain sterility.



Intended Use:	The cassettes / trays are different sizes of the same basic configuration: a rectangular base with latchable cover. The cassettes / trays have perforations to allow sterilant penetration. The cassettes / trays contain silicone inserts in the base and/or cover to hold, organize and protect the surgical instruments within the cassette / tray. Instru-Safe ® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during Amsco V-PRO Low Temperature						
				-		-	erature em cassettes are
	_					•	: Aesculap rigid
	container. The		_			_	
		ir own to	maintain	sterilit	y. A full	list of device r	models is provided
	in table 1.			G/ '1'	.: G .		
	Amsco V-PRO Sterilizer	Standard	Lumen	Non Lui		ems	
	V-PRO 1	Cycle X	Cycle N/A	Cycle N/A			
	V-PRO 1 Plus	N/A	X	X			
	V-PRO maX	N/A	X	X			
	Summit Cassett IN-8823	e Model	Aesculap *JM444	Containe	Model		
	IN-6105		*JM742				
	*Validated by Sumn When using the Aeso the load claims for the	culap contain	ner as a steri	ile barrier	the load (Su		on Systems ONLY. ents), should not exceed
	Lumen size of in	strumenta	tion valida	ated incl	udes:		
	Summit Cas	sette M	inimum Insi	ide N	Iaximum	Number of	
	Model IN-8823		iameter nm		ength 00mm	Lumens 2	
	IN-6105	3r	nm		00mm	1	
	IN-2681	1r	nm	6	4mm	1	
	The worst case v	alidated lo	oad by ver	nt-to-vol	ume calcul	lation is the IN-2	2681 tray.
	The intended us Temperature St		•				O Low n completed for
	the Amsco V-P		•			•	-
	sterilization cyc			afety aı	nd effectiv	veness of the Ir	nstru-Safe
	Instrument Prot			• .	1 1	, • 1	<u> </u>
Comparison of Characteristics	Based on a com	-		_			_
to Predicate	performance, specifications and methods of use, the Instru-Safe Instrument Protection System is equivalent to the identified 510(k) cleared predicate device.						
Device:		- 1				() P	
Element	N	lew Devid	ce			Predicate (K	133015)



Intended Use

Instru-Safe ® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. **Instru-Safe Instrument Protection** System cassettes are intended to allow sterilization of the enclosed medical devices during Amsco V-PRO Low Temperature Sterilization Cycles. The **Instru-Safe Instrument Protection** System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in table 1. Sterilization methods and

configurations

Amsco V-PRO Low Temperature Sterilization Systems

Sterilizer	Standard Cycle	Lumen Cycle	Non Lumen Cycle
V-PRO 1	X	N/A	Ñ/A
V-PRO 1 Plus	N/A	X	X
V-PRO maX	N/A	X	X

Summit Cassette Model	Aesculap Container Model
IN-8823	*JM444
IN-6105	*JM742

*Validated by Summit Medical for use in Amsco V-PRO Low Temperature Sterilization Systems ONLY. When using the Aesculap container as a sterile barrier, the load (Summit tray and contents), should not exceed the load claims for the container in weight or load type. **Instru-Safe Instrument Protection** System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe System cassettes are intended to allow sterilization of the enclosed medical devices during a prevacuum steam sterilization cycle. The Instru-Safe System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. The Instru-Safe System cassettes are not intended on their own to maintain sterility.

Sterilization methods and configurations

• Autoclave Sterilization Parameter:

Cycle: Pre-vacuum

Temperature: 270°F (132°C) Exposure Time: 4 minutes Minimum Dry Time: 30 minutes

Summit Cassette Model	Aesculap Container Model
IN-8823-AE	*JN444
IN-2880	*JK444
IN-6105	*JN742

*Validated by Summit Medical for use in steam prevacuum sterilizers ONLY operating at 270°F (132°C) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization container intended load claims.

					T
	Lumen size of				
	Summit Cassette	Minimum Inside	Maximum Length	Number of Lumens	
	Model	Diameter	Length	Lumens	
	IN-8823	3mm	400mm	2	
	IN-6105	3mm	200mm	1	
	IN-2681	1mm	64mm	1	
	The worst case is the IN-2681		by vent-to- vol	ume calculation	
Material Composition	No changes from predicate device				The cassette contains components made of anodized aluminum, stainless steel, blue
Physical Properties	Instru-Safe Instrument Protection System cassettes include - perforated base - perforated cover - silicone inserts (hold-it / hold down)				Instru-Safe Instrument Protection System cassettes include - perforated base - perforated cover
	HandlesLatchesFeet				- silicone inserts (hold- it / hold
	- Posts (op				down)
	- Divider (-		- Handles	
	- Shelf (op	tional)			- Latches - Feet
Chemical Properties	Not Applicab	le			Not Applicable
Configurations / Dimensions	Various configurations / dimensions				See table located in predicate device
Air permeance Not Applicable Not Applicable					

Percent of surface performations	Not Applicable	Not Applicable
Performance	New Device	Predicate
Sterilant	Amsco V-PRO Low Temperature	Pre-Vacuum Steam
Penetration	Sterilization Systems.	Cycle: Pre-
		vacuum
		Temperature:
		270°F (132°C)
Microbial	Not Applicable	Not Applicable
Barrier		
Properties		
(Packaging		
Integrity)		
Material	No changes from predicate device	Refer to predicate device
Compatibility		K133015
Toxicological	MEM Elution Cytotoxicity (ISO	Refer to predicate device
Properties	10993-5)	K133015
(Biocompatibil	- The test samples meet the USP and	
ity, including	ISO 10993-5 requirements for this	



accelerated shelf life	
ion Parameter:	
m Temperature: inimum Exposure	
Minimum Dry Time:	
The technological characteristics of the subject devices are equivalent to the	
predicate devices. The cassettes / trays are made of standard medical grade	
materials and do not incorporate any new technological characteristics.	
Sterilization validation testing was performed to demonstrate Instru-Safe	
Instrument Protection System compatibility when used in an Amsco V-PRO Low	
Temperature Sterilization Systems with a legally marketed wrap or Aesculap rigid container.	
Based upon intended use, performance data and technical information provided in	
this pre-market notification, the Instru-Safe Instrument Protection System	
described herein is substantially equivalent to the predicate device [Instru-Safe	
Instrument Protection System (K133015)].	
i i z	



Table 1 – Device Models

Part Number	Maximum # of Instruments	Estimated Weight - Tray w/ instruments (lbs)
IN-1315	30	3.5
IN-2006	8	2
IN-2681	13	0.64
IN-2682	13	0.89
IN-2683	13	1.39
IN-2840	36	8.75
IN-2842	24	6.5
IN-2843	36	8.75
IN-2880	56	12.1
IN-2900	22	4.18
IN-2950	12	4.1
IN-3030	34	9.5
IN-4000	20	3.2
IN-4003	30	3.25
IN-4010	10	1.98
IN-5009	8	5
IN-5401	6	2
IN-5401-02	2	1
IN-5401-03	2	1
IN-5401-08	8	3.2
IN-5401-12	12	3.25
IN-6103	2	2.15
IN-6105	2	2.15
IN-6110	3	2.15
IN-6203	2	2.75
IN-6205	2	2.75
IN-6210	2	2.75
IN-6240	2	2.75
IN-6303	2	3.28
IN-6305	2	3.28
IN-6310	2	3.28
IN-6403	2	3.28
IN-6405	2	3.28
IN-6410	2	3.28



IN-6500	30	12.5
IN-7010	2	2
IN-7012	1	1.07
IN-7020	30	8.5
IN-7030	30	10
IN-7032	2	1.1
IN-7073	10	5
IN-7120	45	11.25
IN-7123	45	12
IN-7130	45	13.5
IN-7140	45	14.5
IN-7150	8	1.9
IN-7153	6	1.7
IN-7220	45	14.5
IN-7223	10	9.2
IN-7230	45	14.5
IN-7234	45	14.5
IN-7240	45	14.5
IN-7250	45	14.5
IN-7252	25	8
IN-7260	45	14.5
IN-7273	10	6
IN-7274	30	8
IN-7322	45	14.5
IN-7323	45	14.5
IN-7343	45	14.5
IN-7344	1	4
IN-7360	45	14.5
IN-7423	45	14.5
IN-7452	10	8
IN-7453	10	8
IN-7540	45	14.5
IN-7560	45	14.5
IN-7644	45	14.5
IN-7723	15	7.18
IN-7724	15	7.2
IN-7725	10	9.5



IN-7781	45	14.5
IN-7823	45	14.5
IN-7830	45	14.5
IN-7840	45	13.5
IN-7940	20	13.25
IN-8240	20	13.5
IN-8610	2	6.65
IN-8612	2	6.8
IN-8613	2	6.1
IN-8615	2	5.8
IN-8616	2	5.8
IN-8620	3	7.2
IN-8621	4	7.18
IN-8622	4	7.18
IN-8630	3	6.5
IN-8632	3	6.45
IN-8633	3	6.8
IN-8640	4	5.35
IN-8642	4	5.35
IN-8643	5	5.35
IN-8645	4	5.35
IN-8650	4	5.85
IN-8660	4	5.35
IN-8662	4	5.35
IN-8663	3	5.5
IN-8700	40	14
IN-8810	20	13.5
IN-8820	15	8.75
IN-8823	45	14
IN-8830	15	8.75
IN-8833	45	14
IN-8840	20	13.75
IN-8850	15	8.75
IN-8853	45	14
IN-8860	15	8.75
IN-8862	30	10.5
IN-8863	45	14



IN-8880	2	3.28
IN-8882	16	12.1
IN-8883	2	3.28
IN-8884	4	5.35
IN-8885	1	2.25
IN-8886	6	12.1
IN-8889	6	12.1
IN-8891-S	1	2
IN-8891-SI-12-S	1	2
IN-8891-SI-85-S	1	2
IN-8892	12	12.1
IN-8893	9	7.5
IN-8894	5	16.1
IN-8897	8	6
IN-8898	10	10.25
IN-8899	7	6.5
IN-8901	1	2.25
IN-8902-G2	22	17
IN-8903	15	13.25
IN-8904	22	17
IN-8907	7	12.5
IN-8931	1	2.4
IN-8932	9	9.5
IN-8933	3	3.75
IN-8936	6	11.5
IN-8937	16	14.5
IN-8938	8	12.5
IN-8939	10	11.6
IN-8940	5	5.18
IN-8942	11	10
IN-8943	1	2.7
IN-8944	6	4.7
IN-8945	2	5.18
IN-8946	9	6.1
IN-8980	20	9.5
IN-8982-01	17	9.5
IN-8983-01	16	9.5



IN-8984-01	15	9.5
IN-8986-S	2	6.5
IN-8987-S	2	6.5
IN-8988-S	2	6
IN-8989-S	2	6
IN-9999-160	6	12.1
IN-9999-162-S	2	5.8
IN-9999-168-S	2	5.8
IN-9999-172-S	2	5.8
IN-9999-178-S	2	5.8